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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S 1pg.

Office Action Summary	Application No.	Applicant(s)	
	09/926,397	HAMUNEN, ANTTI	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-65* is/are pending in the application.

4a) Of the above claim(s) *45-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Newly submitted claims 45-65 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The instant claims, unlike the original claimed invention, is drawn to a process for the separation of sterols from neutral substances utilizing a specific apparatus comprising a wiped film evaporator equipped with a rectification column and a short path distillation equipment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-65 were withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

3. The rejection of claims 1-20 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/926,396 is made moot by the cancellation of the instant claims.

4. Claims 21-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 09/926,396. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite processes for the isolation of sterols from neutral substances obtained from soap. The difference is in the recitation of the extraction conditions by the latter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

5. The objection of claim 6 under 37 CFR 1.75(c) is made moot by the cancellation of the instant claim.

6. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claim recites the sterol-rich fraction is obtained as a **bottom fraction**. However, the parent claim is limited to **evaporation fractionating of the neutral substance**. Therefore, the instant claim does not further limit the subject matter of the parent claim.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1-20 under 35 USC 103(a) over Christenson et al. ('810) and Lamminkari et al. ('622) in combination is made moot by the cancellation of the instant claims.

8. Claims 21-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christenson et al. ('810), Lamminkari et al. ('622) and Berry et al. ('797) in combination.

Christenson et al. teach separation of unsaponifiable matter from tall oil residues by (a) extraction of a solution of soaps obtained from a distillation pitch with a solvent, such as naphtha, chlorinated hydrocarbon, ethers etc., to obtain a fraction highly enriched in unsaponifiable matter of the tall oil; (b) washing the extract solution with water; (c) evaporating the solvent from the extract solution and (d) refining the sterol, for example, by crystallization and separation from said crystallization solvent (see the entire article, especially col. 2, lines 38-47; col. 3, Example A; Example IX, especially col. 6, lines 46-67 and Example X, especially col. 6, line 71 – col. 7, line 54).

Lamminkari et al. teach a process for the isolation of sitosterol from the unsaponifiable neutral substances obtained as a byproduct of soap manufactured from the crude soap skimmings of the sulfate pulp process (see the entire article, especially col. 2, line 34 – col. 3, line 14). The reference teaches (a) suspending the neutral fraction and activated carbon in acetone and separating the insolubles and the carbon; (b) distillation of the acetone and recovery of filtrate; (c) redissolving the residue in a

mixture of acetone and alcohol; (d) crystallization by cooling the acetone-ethanol solution and (e) separation of the precipitate (see Examples 1-5 and 8-13).

Berry et al. teach an improved method of crystallizing sterols from mixtures of unsaponifiables such as those obtained from tall oils (see the entire article, especially col. 1, lines 15-19). The process taught by the reference involves the crystallization of sterols utilizing a mixture of water and water miscible solvents such as lower aliphatic alcohols and lower aliphatic ketones following by separation of the sterols and solvents (see col. 2, lines 8-45; Examples 1-4).

Based on the combined teachings of the above cited references, the isolation of sterols from neutral substances by evaporation fractionating/distillation of a hydrocarbon fraction containing said neutral substances in order to obtain a sterol-rich fraction, redissolving said sterol-rich fraction in a water-containing solvent, crystallization from said solvent system followed by separation of the sterol crystals obtained from said solvent would have been obvious to the skilled artisan in the art at the time of the present invention. The motivation would be based on the desire to find optimum reaction conditions in order to obtain unsaponifiable matter in pure form for use as known in the pharmaceutical art. The utilization of a combination of prior art reaction steps in order to obtain a process having optimum reaction conditions is routine in the chemical art. Thus, the claimed process is prima facie obvious.

Claims 24-32 and 39-42 further differ from the cited references by reciting specific reaction conditions such as temperature and ratio of reactants. However, optimization of a reaction by variation in the reaction conditions is routine in the

chemical art and was within the level of skill of the ordinary artisan in the art at the time of the present invention.

Response to Arguments

9. Applicant argues the cited references do not teach (a) evaporation fractionation of neutral substances, (b) crystallization utilizing a water-containing solvent mixture and (c) an optional step involving washing with water. Applicant's argument was considered but not persuasive for the following reasons.

Applicant's argument that the prior art teaches removal of the solvent and not the neutral substances is noted. However, (a) in the process taught by Lamminkari, the solvent is distilled off (see especially, col. 2, Step 2) and (b) under similar reaction conditions and the utilization of similar solvents, the skilled artisan would expect the distillation of similar products. In addition, the outcome of evaporation fractionation, whether of the solvent or the neutral substances, results in a separation process and the production of a sterol-rich fraction. Thus, evaporation fractionating the neutral substances and not the solvent is not a patentable distinction in the absence of a showing of criticality.

Applicant also argues Christenson nor Lamminkari teaches crystallization utilizing a water-containing solvent mixture. As indicated above in #8, utilizing a water-containing solvent in the crystallization of sterols was known in the art at the time of the present invention. According to Berry, the addition of a small amount of water miscible solvent in combination with water affects the crystal structure of the sterols and results

in advantages such as rapid filtration of the mixture and obtaining a drier and more pure final product (see col. 1, line 54 – col. 2, line 12).

Lastly, applicant argues the present invention, unlike Christenson, claims an optional step involving washing with water. Applicant's argument is noted but not relevant since the present invention, like Christenson, would include a washing step.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
February 25, 2004